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TO: Examiner Blessing M. Fubara
Group Art Unit 1618

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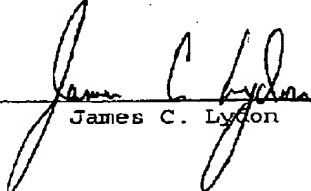
FROM: James C. Lydon

RE: Reply Brief
U.S. Patent Appln. S.N. 09/913,643
By: Mika JOKINEN et al.
Atty. Case No.: TUR-115

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re the application of:

Mika JOKINEN et al.

Serial Number: 09/913,643

Group Art Unit: 1618

Filed: October 19, 2001

Examiner: Fubara, Blessing M.

For: BIODEGRADABLE CERAMIC FIBRES FROM SILICA SOLS

REPLY BRIEF

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INTRODUCTION

The Examiner's Answer mailed February 7, 2008 ("Answer") includes new arguments addressing whether the claims adequately distinguish the inventive fiber from the prior art and the dissolution rate kinetics of the claimed fiber. It also raises a preliminary issue regarding the sufficiency of Appellants' Brief filed November 6, 2007 ("the Brief").

PRELIMINARY ISSUE

The Answer argues the Brief is "deficient" under 37 C.F.R. § 41.37(c)(1)(v). Answer, page 2, heading No. 5, first sentence. However, the Examiner should not have issued an Answer if she believed the Brief does not comply with 37 C.F.R. § 41.37(c). Instead, she should have notified the undersigned of the reason(s) for non-compliance and set a time period to file an amended brief, as required by 37 C.F.R. § 41.37(d).

The Answer argues the Brief is deficient because claim 30 does not claim conditions or process steps, starting viscosity of the silica sol, or how the starting point of the fiber spinning process is controlled (Answer, page 3, lines 1-8). This argument goes to the merits of claim 30, and not to whether the Brief complies with 37 C.F.R. § 41.37(c)(1)(v).

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In fact, the Brief complies with 37 C.F.R. 41.37(c)(1)(v). See the concise explanation of the subject matter of claim 30 at page 4, last paragraph. The Answer's criticism of the Brief as "deficient" is an improper¹ attack on claim 30 rather than a legitimate objection to the Brief.

ARGUMENT

A. PROCESS AND STRUCTURAL LIMITATIONS ARE NOT REQUIRED TO DISTINGUISH APPELLANTS' FIBER FROM THE PRIOR ART

Claims 30² and 32 (from which all other claims depend directly or indirectly) define a biodegradable silica fibre both in terms of the process by which it is made and by a solubility rate range in simulated body fluid. The inventors have unexpectedly discovered the biodegradability of silica fibers can be varied - even when using the same recipe - by adjusting or controlling the

¹The Examiner should have rejected claim 30 under 35 U.S.C. § 112 if she believed the claim is deficient. See 37 C.F.R. § 41.39(a)(2).

²30. (Previously presented) A biodegradable silica fibre spun from silica sol, a biodegradation rate of said fibre being adjusted by controlling the starting point of the spinning process by a viscosity of the silica sol wherefrom the fibre is spun, said fibre having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h.

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viscosity of the spinning solution (Specification, page 5, lines 6-10).

The Answer attempts to justify the obviousness rejections by arguing the claims do not recite process features such as spinning temperature, silica concentration in sol or a starting sol viscosity for the fiber spinning process. See the Answer at page 11, lines 2-7 and page 13, lines 19-22. However, process limitations such as spinning temperature cannot distinguish a product-by-product claim from a prior art product. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985); see also MPEP § 2113.

The Answer also argues the claims do not recite structural features such as pore size. However, a structural limitation such as porosity is not necessary to define the claimed fiber over the prior art. The claimed fiber's solubility rate in simulated body fluid of 0.2 to 20 wt-%/h is a physical property limitation which patentably distinguishes the claimed fiber from the prior art silica fibers disclosed in PCT Patent Publication WO 97/45367 to Ahola et al. ("Ahola et al.") and German Patent DE 196 09 551 ("German '551'"). See the points made in the Brief and paragraph No. 14 of Dr. Jokinen's Declaration filed June 12, 2007.

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1. The Claimed Fibers Are Different
From the Prior Art

Appellants agree with the Examiner that the solubility of silica in simulated body fluid does not change. Therefore, silica fibers having different dissolution rates under identical conditions must be structurally different from one another. Nothing else can explain the difference in dissolution rates.

2. The Claimed Solubility Rate Range
Distinguishes The Prior Art Fibers

One does not need to know the average particle size of a powdered sugar to determine whether it dissolves more rapidly in a cup of coffee than the same amount of sugar in the form of a cube. Similarly, a given silica fiber either dissolves in simulated body fluid quickly enough to satisfy the claimed solubility rate range, or it does not. One does not have to measure a silica fiber's porosity or some other physical parameter to determine whether it satisfies the claims on appeal.

The Answer's arguments that the solubility range does not distinguish the prior art fibers are without merit for the reasons set forth in the Brief and the additional reasons discussed below.

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**B. ONE OF ORDINARY SKILL IN THE ART WOULD UNDERSTAND
THE CLAIMED FIBER'S SOLUBILITY RATE IS ZERO ORDER**

A feature of claims 24-33 is a biodegradable silica fiber having a solubility rate in simulated body fluid of from 0.20 to 20 wt-%/hour. Appellants have noted their fiber will completely dissolve in about 21 days at its slowest solubility rate.³ The Answer argues there is no explicit disclosure the fiber's dissolution rate is zero order or that the fiber dissolves completely within 21 days at its slowest dissolution rate, and speculates the fiber's dissolution rate may be first or second order.

In fact, the dissolution rates of silica fibers in simulated body fluid (wt%/h) were calculated from the linear portion of the dissolution curves, prior to reaching the saturation level. See the first footnote of Table 3 (Specification, page 15).

First and second order dissolution rates could only be calculated from the start and endpoints of the nonlinear portions of the dissolution curves. Accordingly, one of ordinary skill in the art would understand the claimed solubility rate to be zero order.

³In contrast, German '551 discloses a 10 micron diameter silica fiber which is completely degraded within 50 to 500 days.

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Appellants' claims recite a solubility rate range in simulated body fluid which patentably distinguishes the Ahola et al. and German '551 fibers. One of ordinary skill in the art would understand the claimed solubility rate to be zero order.

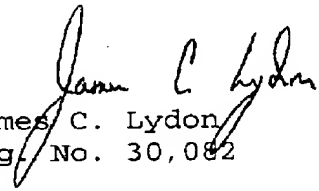
The Answer's remaining arguments are fully rebutted by the points made in Appellants' Brief. In short, the Patent Office has erroneously assumed the solubility rate of a silica fiber is based solely on its chemical composition per se. The application contains experimental data demonstrating silica fiber solubility can be varied by changing the point at which fiber production begins based on the viscosity of the spinning solution from which the fiber is drawn. Neither Ahola et al. nor German '551 disclose or suggest the claimed, rapidly-dissolving silica fiber or how to make it. German '551 teaches away from the use of a high viscosity, low silanol content sol to spin a fiber having a fast solubility rate. Finally, those of ordinary skill in the art would consider a silica fiber having a solubility rate of from .20 to 20 wt-%/h to be unexpected and surprising in view of the state of the art just prior in time to the Appellant's invention.

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Accordingly, this Board is respectfully requested to reverse the rejections of claims 24-33 and pass this application on to allowance.

Respectfully submitted,


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